

REMARKS

The Amendments in the Claims and Prior Art Rejections and Claim Objections

The rejected claims are amended. The prior art rejections are moot. No admission about the patentability of these claims is made. Applicants elected to amend the rejected claims without prejudice or disclaimer to further the prosecution of this application. Applicants reserve the right to continue prosecution of the cancelled subject matter in a possible later related application.

In claim 2, $R_2 = C_3-C_{30}$ alkyl. In new claim 91, which has similar scope as claim 2 before the current amendment, $R_1 \neq C(O)CH_3$.

In claim 12, $R_2 = C_2-C_{12}$ alkyl. In new claim 92, which has similar scope as claim 12 before the current amendment, $R_5 = C_2-C_8$ alkyl.

In claim 34, $R_2 = C_3-C_{30}$ alkyl. In new claim 93, which has similar scope as claim 34 before the current amendment, $R_1 \neq C(O)CH_3$.

In claim 55, $R_6 = C_2-C_8$ alkyl. In new claim 94, which has similar scope as claim 55 before the current amendment, $R_2 = C_3-C_{30}$ alkyl.

In claim 15 a typographical error is corrected.

The claim objections to claims dependent on rejected claims are moot in view of the amendments to the independent claims they depend from.

The Rejections Under Section 101 and 112, first paragraph

The rejections are made over the embodiments wherein X is nitrogen because it is alleged no example is provided in the specification for the preparation of a compound wherein X is nitrogen.

For additional support that demonstrates that one of ordinary skill in the art is able to place a nitrogen group on a compound that is similar to the ones claimed applicants previously submitted a copy of the Journal of Medical Chemistry, 1991, Vol. 34, No. 4, pages 1503-1505.

In response, the Office Action alleges that because the claims do not encompass the compound of the previous reference, it does not cure the enablement rejection. Applicants respectfully disagree. While the compound is not within the scope of the claims and does not present a prior art obviousness issue, it has a similar structural feature, i.e., it contains a phenyl moiety which is substituted with

-C=C(CN)(CONH), wherein the bolded N corresponds to the X in the presently claimed subject matter. This substituent is identical to the substituent on some of compounds of the present invention where X is nitrogen, which allegedly are not enabled. Thus, the existence of this compound in the prior art, while falling outside the scope of the present claims is highly relevant in demonstrating that one of ordinary skill in the art is able to prepare compounds of the invention wherein X is nitrogen.

The preparation of said compounds are routine for one of ordinary skill in the art, and thus, their synthesis methods/protocols need not be described in the specification. "A patent need not teach, and preferably omits, what is well known in the art." *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (CA FC 1984). No undue experimentation is necessary for one of ordinary skill in the art to prepare compounds of the invention wherein X is NH. Thus, the claims are enabled.

The courts have placed the burden upon the PTO to provide evidence shedding doubt on the disclosure that the invention can be made and used as stated; see, e.g., *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971) (holding that how an enabling teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.) The disclosure must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statement contained therein. See *In re Marzocchi*, supra. No such evidence or reason for doubting Applicants' disclosure is provided. The only basis of the rejection is that no example is provided. There is no evidence to support the rejection. The absence of examples of all of the compounds claimed is insufficient evidence to support a rejection under sections 101 and 112, first paragraph.

There is no requirement that an applicant provide examples directed to the preparation of each and every species of a claimed invention. See, for example, *In re Angstadt*, 537 F.2d at 502-03, 190 USPQ 214 (CCPA 1976) (deciding that applicants "are not required to disclose every species encompassed by their claims even in an unpredictable art"); *Utter v Higara*, 845 F.2d at 998-99, 6 USPQ2d 1714 (CAFC 1988) (holding that a specification may, within the meaning of Section 112, Para. 1, enable a broadly claimed invention without describing all species that claim

encompasses). Instead, as discussed earlier, there is no requirement for any examples. See, for example, *Marzocchi*, supra, stating that “an enabling teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.” The MPEP also agrees by stating that “compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed.” See MPEP § 2164.02.

The PTO has failed to meet its burden of establishing that the disclosure does not enable one skilled in the art to make the compounds recited in the claims. Instead of relying on proper probative evidence, the rejection is improperly based on the bare allegation that the disclosure does not provide enablement for X equal nitrogen because such is not exemplified. No evidence has been presented which would demonstrate that the preparation of the allegedly not enabled compounds claimed requires undue experimentation by one of ordinary skill in the art.

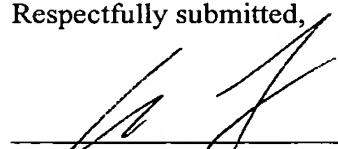
With regard to *Wands*, supra, discussed by the Examiner in the rejections, the court therein teaches that whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. Factors to consider whether a disclosure requires undue experimentation is summarized to include the 8 *Wands* factors (not reproduced here). No factor alone is determinative. The court in *Wands*, further held that the test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine.

Instead of relying on proper probative evidence, the rejection is improperly based on bare allegations and conclusory statements about the adequacy of the disclosure. The basis for the rejection appears to be the lack of examples directed to the preparation of the claimed subgenus of compounds wherein X is nitrogen, which is not a proper basis for section 101 and 112, first paragraph, rejections.

Reconsideration is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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